Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-7 are pending in the application, with claim 1 being the independent claims. Claims 8-23 are cancelled without prejudice to or disclaimer of the subject matter therein. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 8 and 9 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Applicant has cancelled claims 8 and 9. Applicant respectfully traverses this rejection as it may be applied to the pending claims.

The Office Action stated that

> the specification, while being enabling for a method of identifying immunogenic gene products, does not reasonably provide enablement for a method of identifying therapeutic gene products. . . The claims are not enabled because determining what compounds are immunogenic does not mean that the compounds are therapeutic. In order to show that a compound is therapeutic, the practitioner must run further tests to determine which of the immunogenic particles may be used to treat or inhibit the target infection. Because the method does not include such a step, the method is not enabled for screening for therapeutics.

Paper No. 10, page 2.

Applicant has amended claim 1 to recite a "method for screening for potential therapeutics." Methods of determining differential expression, as well as methods for determining immunogenicity are well known in the art and described in the specification. One of skill, using the method of the invention, would be able to identify potential therapeutics for further testing. The method of the invention would enable one of skill to significantly narrow down the field of potential therapeutics.

As Applicant has enabled one of ordinary skill to make and use the invention, withdrawal of this rejection is respectfully requested.

Claims 8 and 9 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. Applicant has cancelled claims 8 and 9. Thus, this rejection is now moot.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-23 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicant has cancelled claims 8-23. Applicant respectfully traverses this rejection as it may be applied to the pending claims.

The Office Action stated that the method of claim 1 "includes both a step of screening an identified host cell gene products for immunogenicity, and determining which of said host cell gene products are immunogenic. It is unclear why these are considered separate steps." Paper No. 10, page 3. Applicant has amended claim 1 to no longer recite both steps.

The Office Action also stated that the term "low level in uninfected cells" is unclear. Applicant has amended the claims as the Examiner suggested.

Applicant has properly addressed the grounds of rejection under 35 U.S.C. § 112, second paragraph. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-4 and 7 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Levinson, U.S. Patent No. 5,721,351 ("the '351 patent"). Applicant respectfully traverses this rejection.

The Office Action stated that

> [t]he 351 patent discloses a method of identifying compounds that modulate expression of genes or the activity of gene products involved in helper T-Cell (TH cell) related disorders . . . The disclosed method centers on the identification of differentially expressed gene products in TH cell . . . Further, the patent teaches methods wherein the identified gene products are screened to determine their ability to ameliorate immune disorder symptoms. Col 45, lines 3-6. Because the patent teaches that some of the identified molecules may be used as therapeutics (col. 5, lines 49-53), and teaches the identification of gene product variably expressed in TH cells and the identification of such molecules that modulate the TH cell phenotypes (col. 45, above), it also inherently teaches a method of screening for immunogenic gene products.

Paper No. 10, pages 5-6.

One of the requirements of the methods of the claims is a step for screening the host cell gene products for immunogenicity. The '351 patent states, at column 45, lines 3-6, that "[c]ell-based and animal model-based assays for the identification of compounds exhibiting such an ability to ameliorate immune disorder symptoms are described below." Immunogenicity and ability to ameliorate immune disorder symptoms are not the same.

One of ordinary skill in the art would understand that a gene product which is immunogenic induces an immune response which is specific against that gene product. A compound which has the ability to ameliorate immune disorder symptoms does not inherently induce a specific immune response against the compound itself.

Nothing in the '351 patent teaches or suggests screening differentially expressed gene products for ability to induce a specific immune response. Thus, the '351 patent does not anticipate the claims. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claim 6 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over the '351 patent in combination with Wang, U.S. Patent No. 6,004,755 ("the '755 patent"). Applicant respectfully traverses this rejection.

As stated above, the '351 patent does not teach nor suggest screening differentially expressed gene products for immunogenicity. The '755 patent does not cure this defect. The '755 patent is directed to methods of determining differential expression of gene products. Nothing in the '755 patent teaches or suggests screening differentially expressed gene products for ability to induce a specific immune response. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 5 was rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Levinson in combination with Staas et al., U.S. Patent No. 6,312,731 ("the '731 patent") and Celis et al., U.S. Patent No. 5,846,827 ("the '827 patent"). Applicant respectfully traverses this rejection.

As stated above, the '351 patent does not teach nor suggest screening differentially expressed gene products for immunogenicity. Neither the '731 patent nor the '827 patent cures this defect. The '731 patent and the '837 patent disclose particular methods of determining immunogenicity. However, nothing in the '731 patent or the '837 patent teaches or suggests screening gene products differentially expressed in infected cells for ability to induce a specific immune response. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1-3 were rejected under 35 U.S.C. § 103 as allegedly being obvious over Levinson in combination with Vournakis et al., U.S. Patent No. 6,399,328 ("the '328 patent") and Shyjan, U.S. Patent No. 6,312,909 ("the '909 patent"). Applicant respectfully traverses this rejection.

As stated above, the '351 patent does not teach nor suggest screening differentially expressed gene products for immunogenicity. Neither the '328 patent nor the '909 patent cures this defect. The '328 and '909 patents are directed to methods of identifying tumor associated gene products through differential expression. Nothing in the '328 patent nor the '909 patent teaches or suggests screening gene products differentially expressed during infection for ability to induce a specific immune response. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be

withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Claims 8-23 were cancelled.

The claims were amended as follows:

1. (once amended) A method of screening for <u>potential</u> therapeutics for infectious diseases, comprising:

(a) identifying host cell gene products selected from the group consisting of: host cell gene products which are upregulated during infection and host cell gene products which are expressed only during infection; <u>and</u>

(b) screening said host cell gene products for immunogenicity[and

(c) determining which of said host cell gene products are immunogenic].

2. (once amended) The method of claim 1, wherein said host cell gene products which are upregulated are expressed at a lowe<u>r</u> level in uninfected cells <u>than in infected cells</u> of the same type.